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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET #	CONFIRMATION NO.
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10/086,213

02/28/2002

Christopher Morgan

16629-3

3448

7590

10/17/2006

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EXAMINER

GAIL GAILENE

ART UNIT PAPER NUMBER

1611

DATE MAILED: 10/17/06

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/086,213	<b>Applicant(s)</b> MORGAN, CHRISTOPHER	
	<b>Examiner</b> Gailene R. Gabel	<b>Art Unit</b> 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4-6,8,11,17-20,25,46,57-59 and 68-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-6,8,11,17-20,25,46,57-59 and 68-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Amendment Entry***

1. Applicant's amendment and response, filed on August 8, 2005, is acknowledged and has been entered. Claims 1-3, 7, 9, 10, 12-16, 21-24, 26-45, 47-56, and 60-67 have been cancelled. Claims 4-6, 8, 11, 17-20, 25, 46, and 57-59 have been amended. Claims 68-73 have been added. Accordingly, claims 4-6, 8, 11, 17-20, 25, 46, 57-59, and 68-73 are pending and are under examination.

### ***Withdrawn Rejections***

2. All rejections and objections not reiterated herein, have been withdrawn.
3. The rejections of claims 1-3, 7, 9, 10, 12-16, 21-24, 26-45, 47-56, and 60-67 are now moot in light of Applicant's cancellation of the claims.
4. In light of Applicant's amendment and arguments, the rejection of claims 4-6, 8, 11, 17-20, 25, 46, and 57-59 under 35 U.S.C. 102 (b) as being anticipated by Zarling et al. (US Patent 5,736,410), is hereby, withdrawn.

### **New Grounds of Rejection**

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4-6, 8, 11, 17-20, 25, 46, 57-59, and 68-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 68, step b) is vague and indefinite in reciting, "said analyte being one which provides the acceptor species bound to the surface" because prior recitation of the acceptor species in (ii) provides that "the acceptor species is bound to the surface of the solid phase". Hence, it is unclear how the analyte provides the acceptor species to the surface of the solid. Based on the recited claims, it is unclear how the acceptor species in (ii) is bound to the surface of the solid phase if per chance, the analyte is not present in the sample. Does Applicant perhaps intend in part (ii), that the acceptor species is either 1) bound to the surface or 2) may be in solution, but is caused to be bound to the surface of the solid phase in the presence of an analyte.

Claim 68, step b) has improper antecedent basis in reciting, "bound acceptor species". Change to "said bound acceptor species" for proper antecedent basis.

Claim 68 is vague and indefinite in being complete in lacking a correlation step in this method of detecting or quantifying an analyte as required by the preamble.

Specifically, it is unclear how an analyte in a sample is differentially detected if present or otherwise, differentially quantified for its concentration. Step c) only recites "detecting luminescence in at least one spectral region of the emission of the donor species or the acceptor species...". Should there be a binding interaction between the analyte and a

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binding partner such as an antibody or an oligonucleotide probe that is specific for the analyte, which is immobilized to the surface of the solid phase, so as to cause or allow the donor species and the acceptor species to perhaps a change proximity between the donor species and the acceptor species and a change in excitation conditions; hence, providing luminescence to be detected or measured. Accordingly, claim 68 is vague and indefinite in failing to specifically define structural and functional cooperative relationships between each one of the donor and acceptor species and the analyte to be detected, so as to be able to provide an actual measure of presence and/or quantitation of analyte in the sample.

Same analogous problems and comments in claims 68, which regards to measuring analyte, apply to all of claims 46, 71, 72, and 73.

Regarding claim 25, the phrase "and other proteins" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "and other"), thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d).

Regarding claim 58, the phrase "and other proteins" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "and other"), thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d).

Regarding claim 59, the phrase "and other proteins" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by

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"and other"), thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 4-6, 11, 17-20, 25, 57, 58, and 68-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zarling et al. (US Patent 5,736,410) in view of Selvin et al. (US Patent 5,622,821).

Zarling et al. disclose luminescence binding assays for performing sensitive detection of analyte. Zarling et al. provide use of up-converting inorganic lanthanide phosphor particles as labels, wherein the lanthanide phosphor particle label absorbs at least two photons at an excitation frequency and subsequently emits electromagnetic energy at an emission frequency higher than the excitation frequency (see column 10, lines 19-36 and column 19, line 65 to column 21, line 5). The up-conversion labels as taught by Zarling et al. provide up-conversion process based on excitation of lanthanide ions in the matrix (see column 14, lines 18-54). Binding of analyte to its binding partner immobilized in the particle matrix carrying the up-conversion label provides detection

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and quantitation of the analyte in the sample (see column 7, lines 39-65). The up-converting lanthanide phosphor particles may be in organic or inorganic polymer form, which is coated with polycarboxylic acid and derivitized with functional groups. The up-converting lanthanide phosphor particles comprise microcrystalline matrix as solid phase, the surface of which has bound thereto antibodies, lectins, or oligonucleotides (probe) or any binding partner specific for selectively binding the analyte (see column 10, lines 55-67, column 13, line 10 to column 14, line 8, and column 22, lines 9-26). The solid phase may be provided or complexed with a metal coating (see column 8, lines 9-23). Zarling et al. specifically teach that the up-converting lanthanide phosphors absorb long wavelength excitation radiation and convert it to emit radiation at a shorter wavelength (one-half to one-third of the excitation wavelength) (see column 5, lines 36-43). The up-converting lanthanide phosphor labels are excited by simultaneous or sequential absorption of two or more photons (multiphotons) having same or different energy (multiphotons) differentiated on the basis of the excitation or emission wavelength spectra (see column 5, lines 44-57 and column 6, lines 7-27). Therefore, the labels can be used to detect and discriminate multiple analyte targets (see column 22, line 58 to column 23, line 30). Up-converting labels, characterized by excitation and emitted wavelengths that are typically infrared or visible portions of the spectrum, permit essentially total rejection of any non-specific background autofluorescence because the long wavelength excitation radiation is converted to emitted radiation at about one-half to one-third of the excitation wavelength.

Zarling et al. differ from the instant invention in failing to teach a luminescence assay based on detection of energy transfer between an energy donor species and an energy acceptor species, wherein the analyte causes a change in the proximity between the donor species and the acceptor species.

Selvin et al. disclose use of lanthanide ions (terbium, europium) complexed with chelates as labels in resonance energy transfer assay methods wherein a change in luminescence is measured, i.e. quenching or decay. Specific analytes in a sample are detected by coupling the chelates to a reagent capable of selectively binding the analyte, which mediates formation or dissociation between donor species and acceptor species (see column 2, lines 31- 61, column 7, lines 27-36 and lines 49-62). Selvin et al. specifically disclose that the lanthanide chelates may be coupled to assay reagents including antibodies, enzymes (catalyze formation or cleavage of a linkage), receptors, etc. and are amenable to luminescence resonance energy transfer to determine presence of analyte in the sample (column 8, lines 23-46).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the teaching of Selvin in luminescence assay based detection of energy transfer of lanthanide ions into the method of Zarling to detect the presence of analyte in a sample which utilizes lanthanide ions as up-converting phosphors to qualitatively and quantitatively determine the presence of analyte because Selvin specifically taught that lanthanide ions which are used by Zarling as up-converting phosphor labels are amenable to luminescence resonance energy transfer methods for assaying the presence or amount of analyte in a sample.



***Response to Arguments***

7. Applicant's arguments with respect to claims 4-6, 8, 11, 17-20, 25, 46, and 57-59 have been considered but are moot in view of the new grounds of rejection.

8. Applicant's arguments filed August 8, 2005 in regards to claim 57 has been fully considered but they are not persuasive.

A) Applicant argues the present invention discloses metal coatings on solid phase on up-converting nanoparticle itself. Applicant contends that Zarling et al. makes no reference of a metal coating of up-converting particles.

Contrary to Applicant's argument, Zarling et al. indeed, makes reference to optional metal complexation or coating of up-converting particles in column 8, lines 9-23.

***Prior Art***

9. Claims 8, 46 and 59 are free of the prior art of record.

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gailene R. Gabel  
Patent Examiner  
Art Unit 1641  
October 2, 2006

